

REMARKS

In the Office Action dated November 5, 2008, the Examiner rejected claims 1-6, 8-10, 12, 13, 15, 18, 19, 21, and 23-32 under 35 U.S.C. § 112 first paragraph as failing to comply with the written description requirement; rejected claims 1-4, 6-12, 18, 19, 21-26, 27-29, 31, and 34 under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,053,003 to Dadson et al. ("*Dadson*") in view of U.S. Patent No. 4,999,885 to Lee ("*Lee*"); rejected claims 5, 13, 15-17, 20, and 30-33 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of U.S. Patent No. 5,820,582 to Keilman ("*Keilman*"); rejected claim 14 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of U.S. Patent No. 4,772,497 to Maasola ("*Maasola*"); and rejected claim 35 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*, and further in view of U.S. Patent Publication No. 2002/0115795 to Shang et al. ("*Shang*").

By this Reply, Applicant has amended claims 1-6, 8-10, 12, 13, 15, 18, 19, 21, and 23-32. Accordingly, claims 1-35 are currently pending in this application. No new matter has been added by this Reply.

REJECTION UNDER § 112

In the Office Action, the Examiner rejected claims 1-6, 8-10, 12, 13, 15, 18, 19, 21, and 23-32 under 35 U.S.C. § 112 first paragraph as failing to comply with the written description requirement. Applicant does not necessarily agree with the Examiner's rejection, however to expedite prosecution, Applicant has amended claims 1-6, 8-10, 12, 13, 15, 18, 19, 21, and 23-32 to remove "non-sterile." Accordingly, Applicant

requests that the Examiner withdraw the § 112 rejection of claims 1-6, 8-10, 12, 13, 15, 18, 19, 21, and 23-32.

REJECTION UNDER § 103(a)

In the Office Action, the Examiner rejected claims 1-4, 6-12, 18, 19, 21-26, 27-29, 31, and 34 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee*. Applicant respectfully traverses this rejection.

Several basic factual inquiries must be made in order to determine the obviousness or non-obviousness of claims of a patent application under 35 U.S.C. § 103. These factual inquiries, set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966), require the Examiner to:

- (1) Determine the scope and content of the prior art;
- (2) Ascertain the differences between the prior art and the claims in issue;
- (3) Resolve the level of ordinary skill in the pertinent art; and
- (4) Evaluate evidence of secondary considerations.

The obviousness or non-obviousness of the claimed invention is then evaluated in view of the results of these inquiries. *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. at 467; see also *KSR Int'l Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385 (U.S. 2007); see also M.P.E.P. § 2141(II).

Applicant traverses the Examiner's rejection at least because the Examiner has not properly determined the scope and content of the prior art and the cited references do not disclose every limitation of independent claims 1 and 27.

Applicant first wishes to provide some background information to the Examiner. There is a large risk of infection associated with peritoneal dialysis (PD) treatment.

(See *Dadson* col. 1, lines 13-14, 38-41, and 61-68.) Therefore, as recited in paragraph [0003] of Applicant's published specification, "a package for use in a peritoneal dialysis treatment must be sterilized. Mostly, steam autoclave sterilization is used for this purpose. The autoclave temperature has to be at least about 120° C during a specified retention time in order to guarantee that all microorganisms are killed." The paragraph continues to explain that there is a risk for deformation of the tubular line elements of the line set, due to the high temperature during sterilization if the line element is, for example, crossed over by another line element.

To overcome these and other problems, independent claim 1 provides for:

"A package for use in a peritoneal dialysis treatment, wherein the package includes a line set, said line set including a first tubular line element, a second tubular line element and at least one component connected to the first and second tubular line elements, the package comprising organizing means configured to organize the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package, wherein the package including the line set is configured to substantially eliminate damage to the package or line set related to sterilization."

Dadson discloses "a stem CB, and two arms AB and BD." (Col. 4, lines. 53-54.) *Dadson* also discloses a "connector 60 [that] mates with the patient's catheter connector." (Col. 5, lines. 66-67.) *Dadson* further discloses that "[o]ne form of this invention is constituted by a package which contains the "Y" set." (Col. 5, lines. 61-62.)

Lee discloses "[a] clip for orderly arrangement and identification of flexible lines such as hospital intravenous tubing has a pocket for grasping the tubing and interengaging protrusions and engagement holes whereby the clip can be chained in a line with other similar clips." (Abstract.)

However, neither *Dadson* nor *Lee* discloses “organizing means configured to organize the line set within the package during sterilization such that no part of the line set extends across another part of the line set during sterilization of the package” (emphasis added), as recited in independent claim 1. The Examiner contends that “*Lee* teaches that it is known to use an organizing means connected to both first A and second B tubular elements and fully capable of being arranged to organize the line set such that no part of the line set extends across another part of the line set (see Figs. 7-10).” (Office Action at 6.) Applicant disagrees. Although figures 7-10 of *Lee* may disclose a clip for orderly arrangement and identification of flexible lines, *Lee* does not disclose, and the Examiner has not shown anywhere in the prior art, the teaching of a package “organizing means” where “no part of the line set extends across another part of the line set” (emphasis added), as recited in independent claim 1. The clip of *Lee* may prevent crossing of the flexible tubing at the clip, but *Lee* does not teach, disclose, or suggest a package where no part of the line set extends across another part of the line set.

In Applicant’s Reply submitted October 14, 2008, Applicant stated that “*Lee* is not configured to keep the flexible tubings from extending across each other at a distance from the clip.” (Reply at 11.) In the most recent Office Action the Examiner asserts that “the features upon which applicant relies (i.e., keeping the flexible tubing from extending across each other at a distance from the clip) are not recited in the rejected claim(s).” (Office Action at 3.) Applicant submits that keeping the flexible tubings from extending across each other at a distance from the clip falls within an “organizing means configured to organize the line set within the package such that no part of the line set

extends across another part of the line set" (emphasis added), as recited in independent claim 1. In other words, if no part of the line set extends across another part of the line set, then it clearly follows that the flexible tubings cannot extend across each other at a distance from the clip.

Furthermore, independent claim 1 also recites that the "package including the line set is configured to substantially eliminate damage to the package or line set related to sterilization." Neither *Dadson* nor *Lee* suggest, teach, or disclose a "package including the line set [that] is configured to substantially eliminate damage to the package or line set related to sterilization."

Independent claim 27 recites, amongst other things, "the step of organizing the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package." As mentioned previously, *Lee* teaches "orderly arrangement and identification of flexible lines such as hospital intravenous tubing." (Abstract.) However, neither *Dadson* nor *Lee* disclose, teach, or suggest "the step of organizing the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package" (emphasis added), as recited in independent claim 27.

Further, *Lee* teaches away from Applicant's invention. *Lee* teaches use of its device during hospital treatment and not during sterilization. For example, *Lee* teaches that "[s]uch tubing . . . can easily become entangled, leading to further confusion as to the origin and destination of particular tubes. These multiple strands of tubing, if not kept orderly, will make an unsightly mess and be a nuisance to both patient and medical personnel." (Col. 1, lines 20-26, emphasis added.) *Lee* also teaches that

"[d]isorganized tubing is prone to catch on passing persons or equipment and can be disengaged accidentally from the patient or the source." (Col. 1, lines 26-28, emphasis added.) However, *Lee* makes no mention of using its device during or in connection with sterilization. Instead, *Lee* teaches away from Applicant's invention by describing use of its device during hospital treatment.

For at least the reasons discussed above, independent claims 1 and 27 are allowable over *Dadson* and *Lee* and Applicant respectfully asks the Examiner to withdraw the § 103(a) rejection of these claims. Accordingly, claims 2-4, 6-12, 18, 19, 21-26, 28, 29, 31, and 34 are allowable at least due to their dependence from allowable independent claim 1 or 27 and due to their additional recitations of patentable subject matter. Thus, Applicant respectfully requests that the § 103(a) rejection of these claims be withdrawn as well.

The Examiner rejected claims 5, 13, 15-17, 20, and 30-33 under 35 U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee* and *Keilman*. *Dadson*, *Lee*, and *Keilman* do not disclose or suggest each and every limitation of the rejected claims. The Examiner contends that *Keilman* teaches "tubular [line] elements . . . [that] are pre-shaped to extend along a desired path." (Office Action at 18.) *Keilman*, however, does not disclose "organizing means configured to organize the line set within the package during sterilization such that no part of the line set extends across another part of the line set during sterilization of the package" (emphasis added), as recited in independent claim 1 or "the step of organizing the line set within the package such that no part of the line set extends across another part of the line set during sterilization of the package" (emphasis added), as recited in independent claim 27. Therefore, *Keilman* does not

overcome the above-mentioned deficiencies of *Dadson* and *Lee*. Accordingly, claims 5, 13, 15-17, 20, and 30-33 are allowable at least due to their dependence from allowable independent claim 1 or 27 and due to their additional recitations of patentable subject matter. Thus, Applicants respectfully request that the § 103(a) rejection of these claims be withdrawn.

The Examiner also rejected claim 14 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee* and *Maassola*. *Dadson*, *Lee*, and *Maassola* do not disclose or suggest each and every limitation of the rejected claim. The Examiner contends that *Maassola* teaches “the bag for medical solutions made of a mixture of polyolefin and an elastomer.” (Office Action at 23.) *Maassola*, however, does not disclose “organizing means configured to organize the line set within the package during sterilization such that no part of the line set extends across another part of the line set during sterilization of the package” (emphasis added), as recited in independent claim 1. Therefore, *Maassola* does not overcome the above-mentioned deficiencies of *Dadson* and *Lee*. Accordingly, claim 14 is allowable at least due to its dependence from an allowable independent claim 1 and due to its additional recitations of patentable subject matter. Thus, Applicant respectfully requests that the § 103(a) rejection of this claim be withdrawn.

The Examiner rejected claim 35 under U.S.C. § 103(a) as being unpatentable over *Dadson* in view of *Lee* and *Shang*. *Dadson*, *Lee*, and *Shang* do not disclose or suggest each and every limitation of the rejected claim. The Examiner contends that *Shang* teaches “the step of placing (exposing) the tube set in a steam autoclave.” (Office Action at 24.) *Shang*, however, does not disclose “the step of organizing the line

set within the package such that no part of the line set extends across another part of the line set during sterilization of the package" (emphasis added), as recited in independent claim 27. Accordingly, *Shang* fails to overcome the deficiencies of *Dadson* and *Lee*. Thus, claim 35 is allowable over the cited references at least due to its dependence from allowable independent claim 27 and its recitations of additional patentable subject matter. Applicant respectfully asks the Examiner to withdraw the rejection of claim 35.

CONCLUSION

In view of the above amendments, Applicant asserts that the entire application is in condition for allowance. A timely notice of allowance is earnestly requested.

The Office Action may contain statements or characterizations with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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